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SUBJECT OBJET

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## Meeting with Johnson & Johnson

For information only. To be read before your upcoming meeting with Johnson & Johnson.

#### Issue

Johnson (&Johnson (&Z) are seeking a meeting with you regarding innovation and investment in the life sciences sector, and the impact that a number of proposed changes, such as the changes to the proposed Patented Medicines Regulations, will have on the sector.

A list of attendees and bios are provided at Annex A.

## Background

Patented Medicines Regulations

The Minister of Health has a mandate commitment to work with the provinces and territories in order to improve access to and affordability of prescription medicines. In support of these commitments, the Government of Canada is taking action to lower the cost of prescription drugs, provide faster access to new drugs that are safe and effective, and support the development of new tools to promote appropriate prescribing. Budget 2017 outlined an investment of \$140.3 million over 5 years, starting in 2017, and \$18.2 million ongoing to support these actions.

The Government's commitments include reducing the prices that Canadians pay for their medicines by modernizing Canada's patented medicine pricing regime.

Canada's patented medicine prices are among the highest in the world, and despite significant changes in the pharmaceutical market, the Patented Medicines Regulations have not been substantively undated in over two decades.

s.21(1)(b)

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On Desember 2, 2017, after pre-consultation with industry and stakeholders, the Government published its regulatory proposal to amend the Patented Medicines Regulations in Canada Gazette, Part 1. The proposal would update the current regulations by including new price regulatory factors and patentee price reporting requirements to enable the PMPRB to better protect Canadians from excessive prices. The changes would remove the United States – which has the highest drug prices in the world – and Switzerland from the list of countries that the PMPRB uses to benchmark prices, and add countries where drug prices are not excessive. The proposed amendments also put less weight on international comparisons and more on a drug's value for money.

## Government of Canada Innovation Investments in Life Sciences

The Canadian life sciences sector is an important contributor to Canada's innovation economy, engaging in creating the medical innovation that will improve health-care delivery and patient care in Canada and abroad. Statistics Canada does not define and measure the "life sciences sector" as it is broad and encompasses a range of sub-industries. However, it is generally accepted to include drugs and pharmaceuticales production, medical devices and equipment manufacture, and research, testing, and medical laboratories. PricewaterhouseCoopers (PwC) indicates that the life science sector is the fifth largest industry group in Canada, employing 1.3 million people and contributing \$117.2 billion to Canadian gross domestic product (or 7 per cent of the total economy).

Budget 2017 highlighted the health and bio-sciences sector as a key area of the Government's Innovation and Skills Plan and the Government has since established a Health/Sio-sciences Economic Strategy Table to lay out strategies to position Canada to be a global leader in health/bio-sciences innovation. A number of programs exist across the innovation, Science and Economic Development portfolio that benefit life science industries. These programs emphasize such factors as technology, talent, and scaling-up. An overview of these programs is provided in Annex B.

#### Considerations

Patented drug prices in Canada are currently among the highest in the world. Among all OECD members, only the United States and Switzetand have higher prices than Canada. Prices in most wealthy OECD member countries are between 20 per cent and 30 per cent below those in Canada. High patented drug prices in Canada reflect industry developments such as the emergence of, and dramatic increase in, the incidence of high cost drugs. Drugs with annual per patient costs of at least \$10,000 now account for more than 40 per cent of all spending on patented drugs in Canada. where itself 10 years ago they accounted for about 8 per cent.

Despite Canadians paying relatively high prices, the organization which represents J&J and the brand name pharmaceutical industry, Innovative Medicines Canada (IMC), have been advocating that the proposed Peatnetal Medicines Regulations could be costly to the industry and add a high degree of complexity for patent medicines to enter the Canadian market. IMC has publicly stated that the proposed regulations could cost the industry up to \$26 billion over a ten-year period but has not publicly released its analysis in order for this figure to be validated.

Recognizing the Government intends to proceed with the regulations this year, J&l has indicated that they have prepared a proposed solution, which the company suggests will address the Government's related concerns with the sector, including the appropriate use of pharmaceuticals, un-funder-insured populations, and investments in innovation. Documents have not been shared by J&f in advance.

They are likely to highlight the importance of innovation and point to current investments such as JLABS@Toronto, an innovation incubator collaboration between J&J, academic institutions such as University of Toronto, hospitals and the Ontario government. Annex C provides further details on the JLABS@Toronto initiative.

## Key Messages

- The Government is committed to improving the accessibility, affordability and appropriate use of drugs.
- Industry is encouraged to come to the table as a partner so we can all work towards
  meeting health care needs while also supporting innovation.
- Health Canada is the lead on the Government's proposed amendments to the Patented Medicines Regulations.

s.21(1)(a)

## ANNEX A: BIOGRAPHICAL INFORMATION

 Dr. Lesia Babiak, Executive Director, Worldwide Government Affairs & Policy (Canada) and Chair, Government Affairs Council for the Johnson & Johnson Family of Companies in Canada

In her current role, Dr. Babiak chairs the cross sector J&J Canada Government Affairs Council. She also holds responsibilities for the Government Affairs Group of the Diabetes Care Franchise in Canada. She has been with Johnson and Johnson since 2000. She has been active in a number of committees and boards including: Chair, BIOTECanada; Health Advisory Board Member of various industry associations such as Rx&D and MEDBC. She served with the Ministry of Health in Ontario as the Associate Director with the Drug Programs Branch. Prior to government, she worked for seven years with another life sciences company in a variety of Clinical Research positions.

· Julia Brown, Vice President, Government Affairs & Market Access, Janssen Inc.

Ms. Brown has been with Janssen Inc. for 14 years and is currently the Vice President of Government Affairs and Market Access. Previous roles at Janssen include National Director of Government and Community Relations, Director of Health Economics and Reimbursement and Director of Government Relations, Ontario/Atlantic. Ms. Brown also serves as the President of the Canadian Association for Healthcare Reimbursement (CAHR) and been a member of the CAHR Board of Directors for 11 years. She served as a Chief of Staff in the Ontario Provincial Government from 1997 to 2003 in the portfolios of Municipal Affairs and Housing. Management Board and Natural Resources.

 Carole Watson, Director, Strategic Pricing, Government Affairs and Market Access, Janssen Inc.

Public biographical information not available.

# - 5 -ANNEX B: OVERVIEW OF FEDERAL INNOVATION PROGRAMS

- · The Strategic Innovation Fund (SIF) allocates repayable and non-repayable contributions to firms of all sizes across all of Canada's industrial and technology sectors, including health and bio-sciences. The program has a budget of \$1.26 billion over five years.
- The Business Development Bank of Canada (BDC) provides venture capital to Canadian life sciences firms and leverages risk capital. The BDC Healthcare Venture fund is focused on early and seed stage life science companies, with initial investments from \$500,000 to \$5 million, and up to \$20 million over the life of the investment.
- The Canadian Foundation for Innovation (CFI) funds infrastructure to strengthen the capacity of Canadian universities, colleges, research hospitals, and non-profit research institutions to carry out research and technology development. Funds are disbursed through a range of CFI programs, including the Major Science Initiatives Fund. As of December 2017, the CFI has provided a total of approximately \$1.9 billion to almost 2.500 projects relating to health sciences research.
- The Networks of Centres of Excellence (NCE) currently support 26 health-related NCEs that foster partnerships between industry, academia, and government in a range of areas that include knowledge mobilization, research commercialization, and the acceleration of life science start-ups.
- Genome Canada provides large-scale investments that develop new technologies. connect the public sector with private industry, and create solutions to problems of national interest in health. Funding opportunities include the Genomic Applications Partnership Program (GAPP), which funds downstream research and development projects from a minimum contribution of \$100,000 to a maximum of \$2 million that address real world opportunities and challenges identified by industry, government not-for-profits and other receptors of genomics knowledge and technologies.

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## ANNEX C: JLABS@TORONTO

- As the first JLABS to open outside the United States, JLABS@Toronto joins a network
  of life science facilities that are based throughout the United States in San Diego (the
  flagship JLABS), San Francisco, Boston and Houston.
- These facilities are home to over 140 early-stage companies advancing pharmaceutical, medical device, consumer and digital health programs. JLABS@Toronto is located on the 13th floor in the MaRS West Tower and is a collaboration among Johnson & Johnson Innovation, The University of Toronto, MaRS Discovery District, Janssen Inc., MaRS Innovation, and the Government of Ontario.
- JLABS @ Toronto opened on May 11th, 2016, the 40,000-square foot facility includes cutting-edge, modular and scalable lab space, state-of-the-art equipment, with access to scientific, industry and capital funding experts.
- The space also features JLABS' inaugural device and digital prototype lab that provides entrepreneurs with access to highly specialized tools and skills building programs to design and develop smart health technologies.

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